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EUROPEAN PATENT APPLICATION

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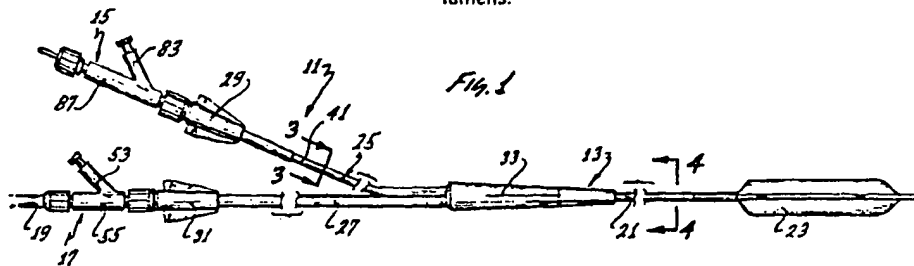
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54 Rapidly inflatable balloon catheter and method.

57 A catheter (13) having first and second lumens and a
 balloon (23) adjacent the distal end of the catheter (13), with
 the first and second lumens extending to the interior of the
 balloon (23). Air can be purged from the catheter (13) by
 introducing a purging liquid in series through the first lumen,

the balloon and the second lumen. Following purging, an
 inflation liquid is introduced in parallel through the first and
 second lumens to rapidly inflate the balloon (23). The balloon
 (23) is rapidly deflated by discharging the inflation liquid
 from the balloon (23) in parallel through the first and second
 lumens.



BACKGROUND OF THE INVENTION

In percutaneous transluminal angioplasty, a dilation catheter is inserted into an artery to dilate the artery. For this purpose, the typical dilation catheter has an inflatable balloon adjacent its distal end and a balloon
5 inflation lumen through which the balloon is inflated and deflated. Inflation is accomplished by forcing an appropriate inflation liquid through the lumen to the balloon, and deflation is accomplished by withdrawing the liquid from the balloon. Inflation of the balloon dilates
0 the adjacent regions of the artery to provide lower restriction to blood flow through the artery.

In carrying out the dilation procedure, it is necessary to repeatedly inflate and deflate the balloon to repeatedly dilate the artery. During the time that the
5 balloon is inflated, blood flow through the artery is blocked. For this reason, it is necessary that the inflation and deflation of the balloon be carried out as rapidly as possible. This is difficult to do because the balloon inflation lumen is long and of small diameter, and
0 consequently, the balloon inflation lumen presents a substantial resistance to the flow of the inflation liquid to and from the balloon.

One other complicating factor is that air must be purged from the balloon before the dilation catheter is used
5 for its intended purpose. This can be accomplished, for example, by inserting a vent tube through the balloon inflation lumen into the balloon. A purging liquid is then introduced through the balloon inflation lumen, and the air

within the balloon is vented through the vent tube. One example of such an arrangement is shown in Simpson et al U.S. Patent No. 4,323,071. One problem with this procedure is that the insertion of the vent tube must be carefully carried
5 out not to damage the balloon and may be cumbersome if the vent tube is attempted to be taken out to obtain a larger inflation lumen.

10

SUMMARY OF THE INVENTION

This invention provides a dilation catheter and method which eliminate the need for vent tube insertion. In
15 addition, with this invention, the balloon of the dilation catheter can be rapidly inflated and deflated so that useful dilation pressure can be applied for the maximum length of time.

This invention provides a catheter assembly adapted
20 to dilate a tubular body member, such as an artery, which comprises a catheter having distal and proximal ends, means for defining at least first and second lumens, and a balloon adjacent the distal end with the first and second lumens extending to the interior of the balloon. The catheter
25 assembly preferably also includes a through lumen that may be used, for example, for a guide wire, monitoring of pressure distally of the balloon, and the infusion of a contrast medium or medication.

To purge air from the balloon, the first and second
30 lumens are used in series. More specifically, a purging liquid is passed in series through the first lumen, the balloon and the second lumen to purge air from the balloon

out through the second lumen. Thus, no insertable vent tube is required.

Thereafter, the first and second lumens are used in parallel for inflating and/or deflating of the balloon.

5 Preferably, the first and second lumens are used in parallel for both inflation and deflation of the balloon. This is accomplished by passing an inflation liquid through both of the first and second lumens to inflate the balloon and discharging the inflation liquid from the balloon through
10 both of the first and second lumens.

The purging of air from the balloon is preferably carried out with the balloon pointed downwardly. Following the purging cycle, the catheter can be inserted into the vascular system of the patient to dilate a region of the
15 vascular system.

The catheter assembly includes means for introducing the purging liquid, means for introducing the inflation liquid and means for discharging the inflation liquid from the balloon. Although these means can be of
20 various different constructions, the catheter preferably includes a connector located proximally of the balloon, and the means for introducing the purging liquid is removably coupled to the connector. This permits such means to be removed from the connector and replaced with the means for
25 introducing the inflation liquid.

In a preferred construction, the means for introducing the purging liquid includes a purge fitting having a first leg communicating with the first lumen at the connector and a second leg receiving the second lumen. The
30 first leg is communicable with a source of the purging liquid. The purge fitting can be removed and replaced with,

for example, a syringe which can introduce the inflation liquid and enable discharge of the inflation liquid from the balloon.

Another feature of this invention is that the
5 distal tip of the catheter through which the through lumen
extends is flexible, of small cross-sectional area and devoid
of sharp shoulders. This facilitates insertion and movement
of the catheter into and through the vascular system and
minimizes the likelihood of damage to the tissue. This
10 feature can be used with advantage with or without the
balloon purging and inflation and deflation features of this
invention.

This feature can be embodied, for example, in a
catheter which includes a catheter body and an extension tube
15 coupled to the catheter body in communication with the
through lumen in the catheter body and having a passage
therethrough which forms an extension of the through lumen.
The balloon has an inflatable portion in communication with a
balloon inflation lumen, attachment portions on opposite
20 sides of the inflatable portion sealed to the catheter body
and the tube, respectively, and an at least somewhat flexible
tubular distal portion extending distally beyond the tube to
form an extension of the through lumen and to define a distal
end of the catheter. The tubular distal portion is
25 preferably of smaller cross-sectional area than the tube and
is smoothly blended into such smaller cross-sectional area to
avoid the presence of any sharp or abrupt corners shoulders.
Preferably, the tubular distal portion is more flexible than
regions of the catheter body adjacent the tube.

30 The invention, together with additional features
and advantages thereof, may best be understood by reference

to the following description taken in connection with the accompanying illustrative drawing.

5

BRIEF DESCRIPTION OF THE DRAWING

Fig. 1 is an elevational view of a catheter assembly constructed in accordance with the teachings of this invention.

Fig. 2 is a partially schematic, longitudinal sectional view through the purge fitting and the associated connector.

Figs. 3 and 4 are enlarged sectional views taken generally along lines 3-3 and 4-4 of Fig. 1, respectively.

Fig. 5 is an enlarged, fragmentary sectional view taken on an axial plane and showing the distal end portion of the catheter.

Fig. 6 is a fragmentary sectional view taken generally along line 6-6 of Fig. 5.

Figs. 7 and 8 are somewhat schematic views partially in section illustrating the purging and inflation cycles, respectively. The proximal through lumen extension is not shown in Figs. 7 and 8.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Fig. 1 shows a catheter assembly 11 which includes a catheter 13, a purge fitting 15 and a Y-fitting 17, both of which are coupled to the catheter. The catheter assembly also includes a conventional guidewire introducer 19
5 partially within the proximal end of the Y-fitting 17.

The catheter 13 includes a catheter body 21, a balloon 23, a vent-inflation extension 25, a through lumen extension 27 and connectors 29 and 31 which define the proximal end of the catheter 13 coupled to the proximal ends
10 of the extensions 25 and 27, respectively. The catheter 13 also includes a sleeve 33 for encasing portions of the extensions 25 and 27 and the catheter body 21.

The catheter body 21 may be in the form of an elongated, flexible, cylindrical tube (Fig. 4) of a suitable
15 plastic material having suitable internal partitions defining portions of balloon lumens 35 and 37 and a through lumen 39. The balloon lumens 35 and 37 extend from the proximal end of the catheter body 21 to the interior of the balloon 23 at the distal end of the catheter body 21 as shown in Figs. 5 and 6.
20 The balloon lumens 35 and 37 are extended proximally of the catheter body 21 by the extension 25 which comprises an outer tube 41 (Fig. 3) and inner tubes 43 and 45 extending through parallel passages 47 of the outer tube. The outer tube 41 extends within the sleeve 33, and the inner tubes 43 and 45
25 are received within the lumens 35 and 37 of the catheter body 21 and suitably retained therein. Similarly, the connector 29 is suitably mounted on the outer tube 41. As shown in Fig. 2, the inner tube 43 terminates at an inner face 49 of the connector 29, and the inner tube 45 extends completely

through a passage 51 in the connector and completely through the connector.

The through lumen 39 is extended proximally by the extension 27 which extends into the sleeve 33 and a proximal portion of the through lumen 39 in the catheter body 21. The sleeve 33 surrounds the extensions 25 and 27 and the catheter body 21 in a known manner. The Y-fitting 17, which is releasably coupled to the connector 31, has a leg 53 which is open to the through lumen 39 to permit the obtaining of blood pressure or blood samples, the infusion of medication, etc. The Y-fitting 17 has a second leg 55 in which the guidewire introducer 19 is mounted to permit insertion of a guidewire (not shown) through the through lumen 39.

The through lumen 39 is extended distally by a tube 57 and a tubular distal portion 59 of the balloon 23 as shown by way of example in Fig. 5. Although various constructions are possible, the tube 57 is received within a distal end portion of the lumen 39 of the catheter body 21 and is retained therein in any suitable manner, such as by an adhesive or heat sealing. The tube 57 is elongated and flexible and may be constructed of a suitable plastic material. The tube 57 has an axial passage 61 extending through it which forms an extension of the through lumen 39. Preferably, radiopaque bands 63 are suitably retained on the tube 57 within the balloon 23 to permit the physician to ascertain the location of the balloon when it is in the patient's vascular system.

The balloon 23, which is adjacent the distal end of the catheter body 21, has an inflatable portion 65, attachment portions 67 and 69 on opposite sides of the inflatable portion 65 which are sealed to the catheter body 21 and the tube 57, respectively, and the tubular distal portion 59. The balloon 23, which is constructed of a

suitable plastic, such as polyethylene, may have the attachment portions 67 and 69 shrunk onto the catheter body 21 and the tube 57. By tightly shrinking the attachment portion 67 onto the catheter body 21, the catheter body may
5 be compressed somewhat radially inwardly to form an inwardly extending annular shoulder 71 which tends to make the periphery of the attachment portion 67 approximately coextensive with the periphery of the catheter body 21. This minimizes changes in cross section along the length of the
10 catheter 13.

The tube 57 extends completely through the inflatable portion 65, which is of larger cross-sectional area than the tube and the catheter body 21. However, the tube 57 does not project completely through the balloon 23 in
15 that the tubular distal portion 59 extends distally of the tube 57 to form the distal end 73 of the catheter 13. The tubular distal portion 59 is of smaller cross section than the tube 57 and is smoothly and gradually blended into such smaller cross section by an inclined annular wall section 75
20 which extends distally from the distal end of the tube 57. The tubular distal portion 59 terminates distally in a cylindrical section 77 which defines a distal port 79 at the distal end 73.

The balloon 23 is integrally constructed, and the
25 tubular distal portion 59 is resiliently flexible. Preferably, the tubular distal portion 59 is more flexible than regions of the catheter body 21 adjacent the tube 57.

First means is provided for introducing a purging liquid to the lumen 35. Although this means can take
30 different forms, in the embodiment illustrated, it includes the purge fitting 15 and a vent tube 81 carried by the purge

fitting. As shown in Fig. 2, the purge fitting 15 is removably coupled to the connector 29 in a conventional manner. The purge fitting 15 is in the form of a Y-fitting having a first leg 83 in communication with the lumen 35 through a common passage 85 and a passage 51 of the connector 29. The inner tube 45, which defines the proximal extension of the lumen 37, extends completely through the passage 51 of the connector 29 and into the passage 85 of a second leg 87 of the purge fitting 15. The vent tube 81 is slidably received within the passage of the second leg 87, and the vent tube slidably receives the proximal end of the inner tube 45 as shown in Fig. 2. The vent tube 81 terminates in a vent opening 88.

With the purge fitting 15 coupled to the connector 29, the catheter assembly 11 can be used to purge air from the balloon 23 as shown in Fig. 7. The first leg 83 is coupled to a source of the purging liquid (not shown), and the distal end of the balloon is pointed downwardly. The purging liquid is then passed in series through the first leg 83, the passages 85 and 51, the lumen 35, the inflatable portion 65 of the balloon 23, the lumen 37 and the vent tube 81. The passing of the purging liquid in series through the lumens 35 and 37 forces the air in the balloon out through the lumen 37 and the vent tube 81 to the atmosphere. The purging liquid is passed in series through the lumens 35 and 37 in this fashion at least until the purging liquid emerges from the vent opening 88. At this time, it is known that all of the air has been purged from the balloon 23.

Means is also provided for introducing an inflation liquid to the balloon 23 and for discharging the inflation liquid from the balloon. Although this means can take

different forms, in the embodiment illustrated, it includes a syringe 89 (Fig. 8) for accomplishing both of these purposes. More specifically, the purge fitting 15 is removed from the connector 29, and the syringe 89 is attached to the proximal end of the connector. The vent tube 81 can be easily removed with the purge fitting 15 by pulling it off the proximal end of the inner tube 45. The syringe 89 includes the usual barrel 91 and plunger 93 which is movable to the right (as viewed in Fig. 8) on a discharge stroke and to the left (as viewed in Fig. 8) in a suction stroke.

With the syringe 89 charged with inflation liquid, the plunger 93 on the discharge stroke introduces an inflation liquid in parallel through both of the lumens 35 and 37 to inflate the balloon as shown in dashed lines in Fig. 8. More specifically, the inflation liquid from the barrel 91 is forced through the passage 51 to the lumen 35 and forced directly from the barrel into the inner tube 45. Similarly, by moving the plunger 93 on the suction stroke, the inflation liquid is discharged from the balloon 23 in parallel through both of the lumens 35 and 37 to deflate the balloon and move the inflation liquid back into the barrel 91. Because both of the lumens 35 and 37 are used in parallel to inflate and deflate the balloon 23, inflation and deflation of the balloon takes place very rapidly.

In use of the catheter assembly 11, air is first purged from the balloon 23 as described above. Next, the catheter is inserted into the vascular system of the patient using known techniques to place the balloon 23 in the region of the vascular system, such as an appropriate artery, which is to be dilated. After the purge fitting 15 has been replaced with the syringe 89, the balloon 23 is inflated as

described above to dilate the desired region of the vascular system and then deflated to discontinue dilation. Inflation and deflation of the balloon 23 are carried out rapidly. The dilation procedure may be carried out repeatedly within
5 the artery before the catheter is removed from the patient's vascular system. The purging liquid and the inflation liquid may be the same liquid and may be any of a variety of known solutions, such as a mixture of Renographen and saline.

During the insertion of the catheter 13, the
10 tubular distal portion 59, being of small diameter, passes through the artery with relative ease. The inclined wall section 75 provides essentially no shoulder that could cause damage to the tissue. In addition, the flexible nature of the tubular distal portion 59 further minimizes likelihood of
15 injury to the tissue.

Although an exemplary embodiment of the invention has been shown and described, many changes, modifications and substitutions may be made by one having ordinary skill in the art without necessarily departing from the spirit and scope
20 of this invention.

C L A I M S

1. A catheter assembly adapted to dilate a tubular body member comprising :

a catheter having a distal end, a proximal end, means for defining at least first and second lumens, and a balloon adjacent the distal end with the first and second lumens extending to the interior of the balloon;

first means mountable on the catheter adjacent said proximal end for introducing a purging liquid to the first lumen whereby the purging liquid can flow in series through the first lumen, the balloon and the second lumen to purge air from the balloon out through the second lumen;

second means mountable on the catheter adjacent said proximal end for introducing an inflation liquid through at least one of the first and second lumens to the balloon to inflate the balloon;

third means mountable on the catheter adjacent said proximal end for discharging the inflation liquid from the balloon through at least one of the first and second lumens to deflate the balloon; and

at least one of said second and third means including means for passing the inflation liquid in parallel through the first and second lumens.

2. A catheter assembly as defined in claim 1, wherein said second means includes means for passing the inflation liquid in parallel through the first and second lumens to the balloon to inflate the balloon and said third means includes means for discharging the inflation liquid from the balloon in parallel through the first and second lumens to deflate the balloon.

3. A catheter assembly as defined in claim 1 or claim 2, wherein said catheter includes a connector located proximally of the balloon and the first means is removably coupled to the connector whereby the first means can be removed from the connector and replaced with the second and/or third means.

4. A catheter assembly as defined in any one of claims 1 to 3, wherein said second and third means include a syringe mountable on the connector, said syringe has pumping and suction strokes, said syringe introducing the inflation liquid to the first and second lumens on the pumping stroke and withdrawing the inflation liquid from the balloon through the first and second lumens on the suction stroke.

5. A catheter assembly as defined in any one of claims 1 to 4, wherein the catheter includes a catheter body, said first and second lumens and a third lumen extend through the catheter body, an extension tube coupled to the catheter body in communication with the third lumen and having a passage therethrough which forms an extension of the third lumen, said extension tube extends partially through the balloon, said balloon having an inflatable portion communicating with the first and second lumens, attachment portions on opposite sides of the inflatable portion sealed to the catheter body and the tube, respectively, and a tubular distal portion extending distally beyond the tube to form an extension of the third lumen and to define the distal end of the catheter.

6. A catheter comprising :

an elongated catheter body adapted for insertion into the vascular system of a patient and having proximal and distal ends, a balloon inflation lumen and a through lumen;

a flexible extension tube coupled to the catheter body in communication with the through lumen and having a passage therethrough which forms an extension of the through lumen;

an inflatable balloon adjacent the distal end of the catheter body; and

said balloon having an inflatable portion in communication with the balloon inflation lumen, attachment portions on opposite sides of the inflatable portion sealed to the catheter body and the tube, respectively, and an at least somewhat flexible tubular distal portion extending distally beyond the tube to form an extension of

the through lumen and to define a distal end of the catheter.

7. A catheter as defined in claim 5 or claim 6, wherein said tubular distal portion is more flexible than regions of the catheter body adjacent the tube.

8. A catheter as defined in any one of claims 5 to 7, wherein the tubular distal portion is of smaller cross section than the tube and smoothly blended into such smaller cross section without an abrupt change of cross section.

9. A catheter as defined in any one of claims 5 to 8, wherein said tube is partly received within the distal portion of the through lumen in the catheter body.

10. A catheter system comprising :

a catheter body having proximal and distal ends, a balloon at or towards said distal end and at least two lumens extending from within the balloon at least to the proximal end of the catheter;

purgings means attached or attachable to the catheter at or towards the proximal end thereof such that purging liquid can be passed in series through one lumen, through the balloon and out through a second lumen to purge air from the balloon;

means attached or attachable to the catheter at or towards the proximal end thereof such that inflation liquid can be introduced into the balloon through at least one of two lumens to inflate the balloon and inflation liquid can be withdrawn from the balloon through at least one of said two lumens to deflate the balloon, said means and said lumens, being arranged such that on inflation or deflation or both the inflation liquid is passed through both lumens in parallel.

11. A method comprising :

providing a catheter having a distal end, at least first and second lumens, and a balloon adjacent the distal end with the first

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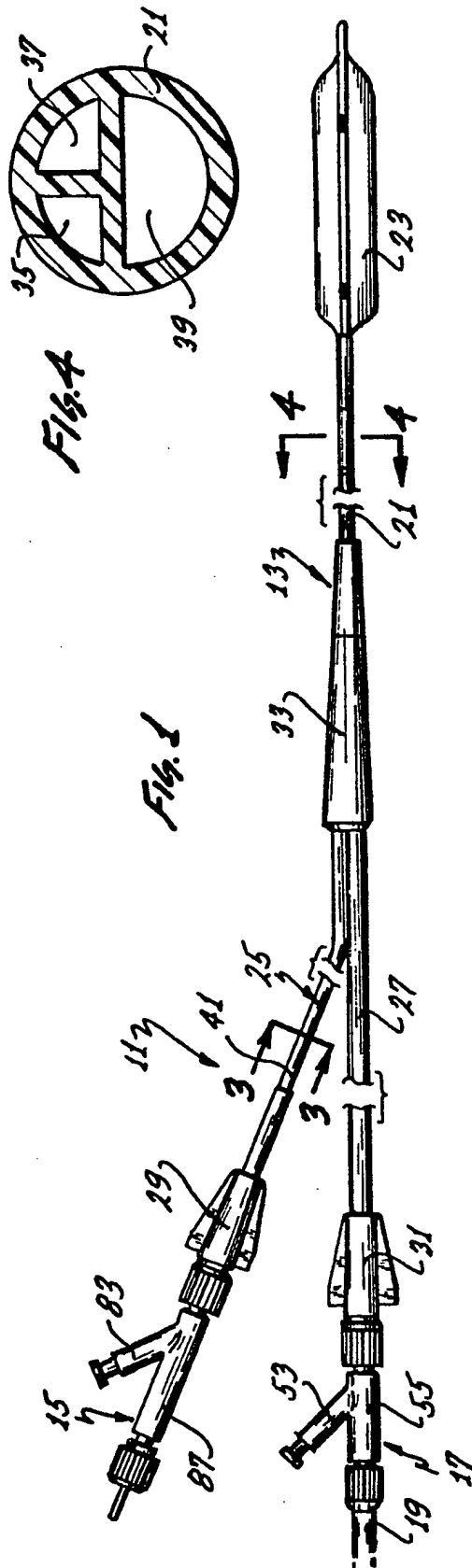
and second lumens extending to the interior of the balloon;

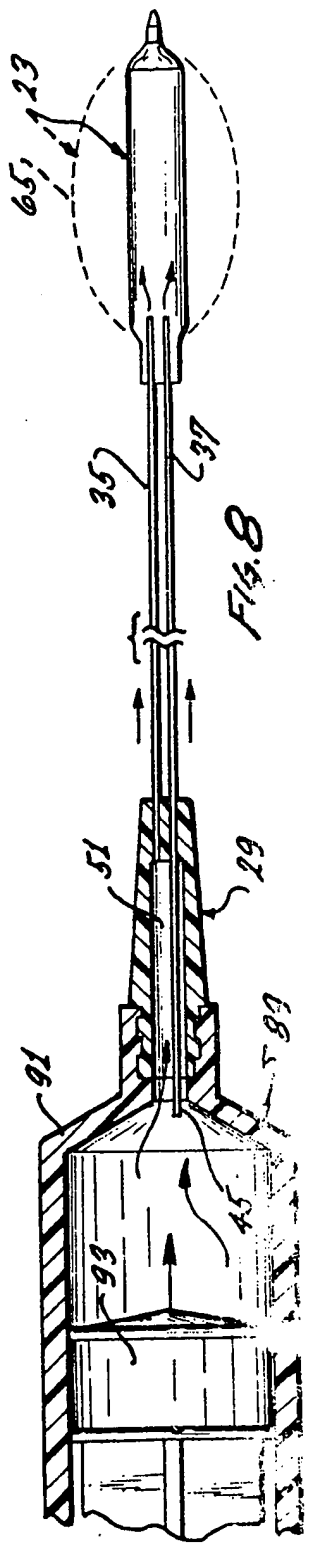
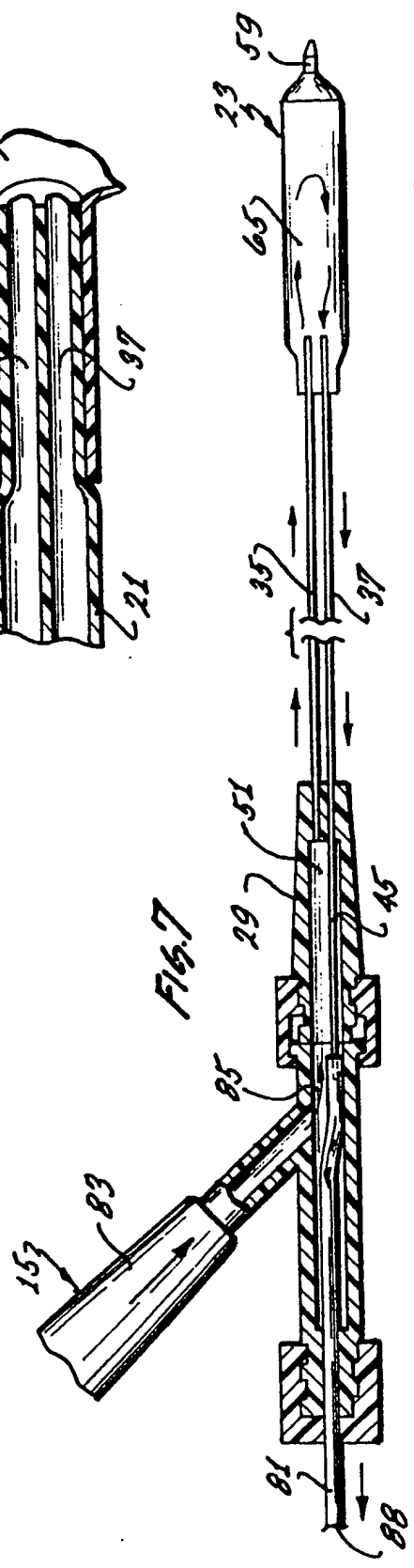
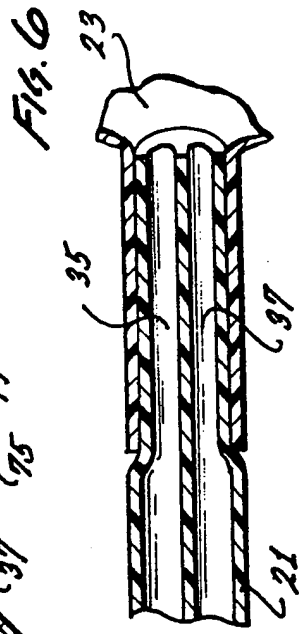
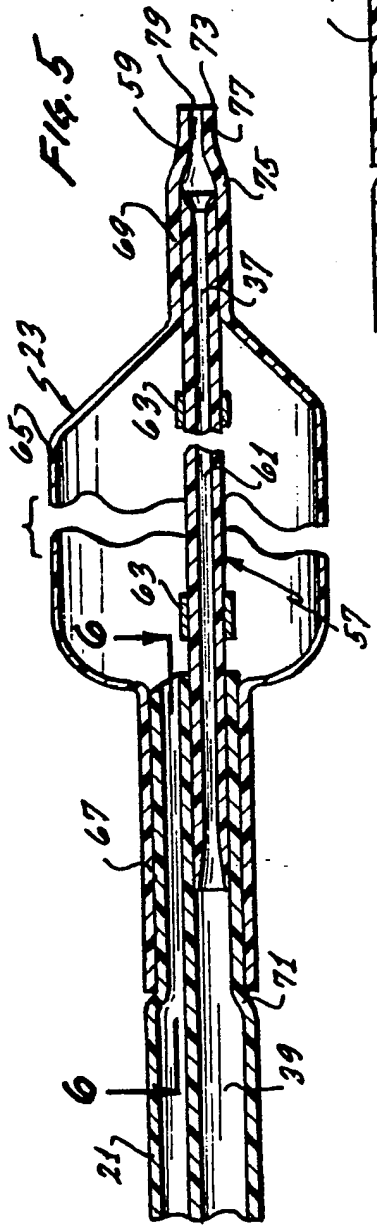
passing a purging liquid in series through the first lumen, the balloon and the second lumen to purge air from the balloon out through the second lumen;

thereafter passing an inflation liquid through at least one of the first and second lumens to the balloon to inflate the balloon;

discharging the inflation liquid from the balloon through at least one of the first and second lumens to deflate the balloon; and

at least one of said steps of passing the inflation liquid to inflate the balloon and discharging the inflation liquid to deflate the balloon including passing the inflation liquid in parallel through said first and second lumens.







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EUROPEAN SEARCH REPORT

0184314

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 85307820.2
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
D,Y A	<p><u>US - A - 4 323 071</u> (J.B. SIMPSON et al.)</p> <p>* Totality; especially fig. 1,3 4,11-14; column 4, line 61 - column 5, line 14; column 6, line 64 - column 7, line 47; column 8, lines 13-37; column 10, line 39 - column 11, line 30; column 12, lines 29-61 *</p> <p>--</p>	1-4,10 11 5,6	<p>A 61 M 29/02</p> <p>A 61 M 25/00</p>
Y A	<p><u>US - A - 2 936 761</u> (H.H. SNYDER)</p> <p>* Totality; especially fig. 2,3,5; column 3, lines 29-52 *</p> <p>--</p>	1-4,10 11 5	
A	<p><u>GB - A - 1 553 915</u> (KENDALL COMP.)</p> <p>* Totality *</p> <p>--</p>	1,6,10 11	<p>TECHNICAL FIELDS SEARCHED (Int. Cl.4)</p>
A	<p><u>US - A - 3 989 571</u> (A. HARAUTVNEIAN)</p> <p>* Totality *</p> <p>--</p>	6	<p>A 61 M 25/00</p> <p>A 61 M 29/00</p>
A	<p><u>GB - A - 1 045 202</u> (PHARMASEAL LAB.)</p> <p>* Totality *</p> <p>--</p>	6	
A	<p><u>WO - A1 - 83/03 204</u> (W. WEBSTER)</p> <p>Totality; fig. 1; page 6, line 34 - column 7, line 3 *</p> <p>--</p>	6	
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 11-03-1986	Examiner LUDWIG
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone</p> <p>Y : particularly relevant if combined with another document of the same category</p> <p>A : technological background</p> <p>O : non-written disclosure</p> <p>P : intermediate document</p> <p>T : theory or principle underlying the invention</p> <p>E : earlier patent document, but published on, or after the filing date</p> <p>D : document cited in the application</p> <p>L : document cited for other reasons</p> <p>& : member of the same patent family, corresponding document</p>			

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